

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.*  
JULIE LONG,

*Plaintiffs,*

v.

JANSSEN BIOTECH, INC.,

*Defendant.*

Civil Action No. 16-CV-12182-FDS

**DEFENDANT JANSSEN BIOTECH, INC.'S SUPPLEMENTAL OBJECTIONS**  
**AND RESPONSES TO PLAINTIFF-RELATOR JULIE LONG'S**  
**INTERROGATORY NOS. 20–22**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, and further to guidance from the magistrate judge concerning Plaintiff-Relator Julie Long's ("Plaintiff's") discovery motions and efforts by counsel for the parties to meet and confer to resolve discovery disputes, Defendant Janssen Biotech, Inc. ("Janssen" or "Defendant") hereby submits these supplemental responses and objections to Plaintiff's Interrogatory Nos. 20–22 as follows.

Janssen's Supplemental Objections and Responses to Plaintiff's Interrogatories are based on Janssen's current information and belief as a result of reasonable searches and inquiries, which are ongoing as necessary. No response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of Plaintiff's Interrogatories, or from modifying or supplementing its responses accordingly.

Janssen's Supplemental Objections and Responses are in addition to and do not waive all objections as to competence, authenticity, relevance, materiality, propriety, privilege, admissibility, and any and all other objections and grounds which would or could require or

permit the exclusion of any document or statement therein from evidence. All such objections and grounds are reserved and may be interposed at any time prior to or at the time of trial.

Janssen has constrained its Supplemental Objections and Responses to the Interrogatories below to the scope defined by the Court's order on phased discovery dated December 14, 2020 ("Phased Discovery Order"). Janssen reserves the right to make further objections to any of Plaintiff's Interrogatories should the Court-ordered scope of discovery change. By objecting now, Janssen does not waive any future objections that might be applicable.

### **GENERAL OBJECTIONS**

Janssen makes each of the following general objections, which it incorporates in its responses to each of the Interrogatories:

1. Janssen objects to the Interrogatories as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.
2. Janssen further objects to Plaintiff's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Plaintiff served 18 enumerated interrogatories on January 19, 2021, which Plaintiff amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; and 14 enumerated interrogatories on May 19, 2021; bringing her total number of interrogatories to 33. When factoring in sub-parts of Plaintiff's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Plaintiff has served, and Defendant has responded to, at least 74 Interrogatories. Fed. R. Civ. P. 33(a)(1) ("Unless otherwise stipulated or ordered by the court, a party may serve on any other party no more than 25 written interrogatories, *including all discrete subparts.*") (emphasis added); *Security Ins. Co. of Hartford v. Trustmark Ins. Co.*, No. 3:01CV2198 (PCD), 2003 WL

22326563, at \*1 (D. Conn. Mar. 7, 2003) (“A subpart is discrete and therefore regarded as a separate interrogatory when it is logically or factually independent of the question posed by the basic interrogatory.”); *Myers v. U.S. Paint Co., Div. of Grow Grp.*, 116 F.R.D. 165, 165 (D. Mass. 1987) (The Court can “strike a set of interrogatories in which subparts are utilized merely for the purpose of evading the limit.”). When incorporating the subparts to Plaintiff’s Definitions and Instructions to her Interrogatories, Plaintiff has served, and Defendant has responded to, over 600 Interrogatories. For ease of reference, Janssen will refer to the interrogatories served by Plaintiff on January 3, 2022, as Plaintiff’s Interrogatories 20–22, but Janssen objects that this designation does not accurately reflect the number of Interrogatories served by Plaintiff during the course of this litigation.

3. Janssen’s inquiry and research into the subject matter of this litigation, and the items requested and enumerated in the Interrogatories, are ongoing. Janssen intends to conduct further inquiry and investigation. No response or partial response contained herein is to be construed as precluding Janssen from further developing or investigating contentions, facts, documents, or any other matter which is the subject of these Requests, or from modifying or supplementing its responses accordingly.

4. Janssen objects to the Interrogatories, Definitions, and Instructions to the extent that they seek to impose obligations or requirements on Janssen which are greater than or different from those imposed by the Federal Rules of Civil Procedure and/or any other applicable law, rule, or regulation.

5. Janssen objects to the Interrogatories to the extent they seek documents or information that are neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence.

6. Janssen objects to the Interrogatories, Definitions, and Instructions, to the extent they are vague, ambiguous, overbroad, or unduly burdensome.

7. Janssen objects to the Interrogatories to the extent they seek documents or information not within the control of Janssen. Janssen's Responses are based on information reasonably available to it, and Janssen will respond to these Interrogatories only on its own behalf.

8. Janssen objects to the Interrogatories to the extent they seek documents or information subject to and protected from disclosure by the attorney-client privilege, the attorney work product doctrine, and/or any other applicable privilege or protection. Janssen objects to the Interrogatories to the extent they seek to elicit documents or information subject to and protected by the settlement, offer to settle, compromise, offer to compromise, or mediation confidentiality privileges. No written response or production of documents which contains information, opinions, documents, or facts subject to any privilege or protection, or references to information, opinions, documents, or facts subject to any privilege or protection, is to be construed as a waiver of the attorney-client privilege, the attorney work product doctrine, or any other applicable privilege, protection, or doctrine for any purpose. Janssen reserves the right to recall from discovery any inadvertently produced document that is protected by the attorney-client privilege, the work product immunity, or any other applicable privilege or immunity. If privileged documents are inadvertently produced, Janssen does not waive or intend to waive any privilege pertaining to such documents, or to any other information or documents.

9. Janssen objects to the Interrogatories to the extent they seek documents that already have been provided to Plaintiff, are publicly available or otherwise equally available to Plaintiff, or would be more appropriately sought from third parties to whom subpoenas or

requests could be directed, or through means that are more convenient, more efficient, more practical, less burdensome, or less expensive.

10. Janssen objects to Plaintiff's Definitions and Instructions to the extent they seek documents or information that would require Janssen to disclose trade secret, proprietary, and/or confidential information, except as provided for in the Protective Order agreed to by the parties.

11. Janssen objects to the Interrogatories to the extent that they incorporate incorrect assertions of fact or law. Janssen's Responses are not a concession that any incorporated assertions or conclusions of fact or law are correct.

12. Janssen objects to the Interrogatories to the extent they seek documents or information outside of the scope authorized in the Phased Discovery Order, including to the extent they seek discovery unrelated to support services provided by Plaintiff during her employment as an Area Business Specialist ("ABS") at Janssen to the physician practices specifically alleged in the Second Amended Complaint ("SAC"). *See* 2d Am. Compl. ¶¶ 175–76, 191–93. While Janssen agrees that documents and information beyond the scope authorized by the Court in the Phased Discovery Order may fall within the scope of subsequent discovery, requests for such documents and information are outside of the scope of the Court's guidance for the narrow initial discovery that was to be the subject of Plaintiff's immediate requests. As such, Janssen objects to each Interrogatory to the extent that it seeks documents or information beyond the scope of the Phased Discovery Order.

13. Janssen objects to the definitions in Plaintiff's Instruction 3(a), (i), (l), (n), (o), (p), (q), (s), (u) and (w) as vague, ambiguous, overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.

14. Janssen objects to the definition of “Electronically stored information” or “ESI” in Plaintiff’s Instruction 3(k) as overbroad and unduly burdensome. All productions of ESI made by Janssen pursuant to these Interrogatories will be made in accordance with, and subject to the provisions of, the ESI Protocol agreed to by the parties.

15. Janssen objects to Plaintiff’s Definitions and Instructions, including Plaintiff’s Instructions 3(i), 3(l), 3(w), and 6, to the extent they seek to impose obligations on entities that are distinct from Janssen, including, but not limited to, Janssen’s parents, U.S. and non-U.S. subsidiaries, divisions, affiliates, predecessors, successors, agents, partners, limited partners, and independent contractors. By defining Janssen and “Defendant” to include entities that are distinct from Janssen and not parties to this action, Plaintiff improperly conflates Janssen with distinct entities that are third parties. Therefore, Janssen construes “Janssen,” “Defendant,” “You,” and “Your” to refer only to Janssen and its employees. Janssen will respond to the Interrogatories based on a reasonable inquiry of individuals expected to possess the requested information.

16. Janssen objects to Instruction 12 to the extent it purports to impose requirements beyond those prescribed by Rule 26(b)(5) of the Federal Rules of Civil Procedure. Janssen will log requested documents withheld from production as required by Rule 26(b)(5) and in accordance with, and subject to the provisions of, the Protective Order agreed to by the parties.

17. Janssen objects to Instructions 14(b) and 14(c) to the extent they seek information not reasonably available to Janssen from internal employment records as overbroad, unduly burdensome, not calculated to lead to the discovery of admissible evidence, and beyond the scope authorized in the Phased Discovery Order.

18. Janssen objects to Plaintiff's Interrogatories, Definitions, and Instructions, including Plaintiff's Instruction 8, to the extent they seek information before October 28, 2006 as outside the scope of this phase of discovery under the Phased Discovery Order.

19. Janssen objects to these Interrogatories to the extent they request information that is "not reasonably accessible because of undue burden or cost" under Fed. R. Civ. P. 26(b)(2)(B), including to the extent they request information that is in archived systems, files, or storage.

### **RESPONSES TO INTERROGATORIES 20–22**

#### **INTERROGATORY NO. 20:**

State whether you contend that when you provided each of the various types of IOI Support and IOI Support Programs that you had a good faith belief that your actions did not violate any law, statute, or regulation, and if so set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

#### **RESPONSE TO INTERROGATORY NO. 20:**

In addition to the foregoing General Objections, Janssen objects to this Interrogatory as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

Janssen further objects to Plaintiff's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Plaintiff served 18 enumerated interrogatories on January 19, 2021, which Plaintiff amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; and 14 enumerated interrogatories on May 19, 2021; bringing her total number of interrogatories to 33. Janssen responded to Plaintiff's interrogatories on February 18, 2021, May

3, 2021, June 22, 2021, and August 4, 2021. When factoring in sub-parts of Plaintiff's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Plaintiff has served, and Defendant has responded to, at least 74 Interrogatories. When incorporating the subparts to Plaintiff's Definitions and Instructions to her Interrogatories, Plaintiff has served, and Defendant has responded to, over 600 Interrogatories.

Janssen further objects to this Request to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen further objects that this Interrogatory is vague, ambiguous, overbroad, and unduly burdensome in its reference to "each of the various types of IOI Support and IOI Support Programs," "any law, statute, or regulation," and "all facts, documents, and evidence." *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) ("Contention interrogatories may be held unduly broad if they ask in an undifferentiated way for 'all' facts or witnesses that support an opposing party's case."). Janssen also objects to this Interrogatory in its entirety as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence.

Janssen further objects to this Interrogatory on the ground that it is a premature contention interrogatory. Discovery and investigation are ongoing, and Janssen therefore objects to this Interrogatory to the extent it purports to require a response prior to the period immediately before the end of this phase of fact discovery. *See generally McCarthy v. Paine Webber Group, Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996).



Janssen further objects that the statutes and regulations at issue in this matter speak for themselves. Janssen also objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at \*3 (D. Mass. Feb. 6, 2018); *Iantosca v. Benistar Admin Servs., Inc.*, No. 08-11785-NMG, 2012 WL 220224, at \*3 (D. Mass. Jan. 24, 2012).

Janssen further objects to this Interrogatory on the grounds that it has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

Notwithstanding the foregoing general and specific objections, Janssen responds that, at the time the product support services were provided, and through the present, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a–7b, and False Claims Act (“FCA”), 31 U.S.C. §§ 3728-3733. The legality of the programs is supported by the publicly available guidance materials from relevant government agencies, which have consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also* Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013). Furthermore, on multiple occasions, the Office of Inspector General, U.S. Department of Health and Human Services (“OIG”) has found that the AKS is not implicated by comparable programs and services. *See* OIG Advisory Opinions and

judicial decisions cited in Janssen's Motion to Dismiss Plaintiff's Second Amended Complaint ("Janssen's Motion to Dismiss"), ECF No. 59, at 6, 8–12.

Janssen further responds that its good faith and reasonable efforts to comply with the AKS and FCA are demonstrated by practices and standards of its Health Care Compliance ("HCC") department applicable to ABS engagement with physician practices. Tom Cornely served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Janssen has searched for and is producing relevant, non-privileged guidance and policies that can be located after a reasonable search.

Janssen further responds that its good faith and reasonable efforts to comply with the AKS and FCA are demonstrated by the fact that medical education and patient support resources go through an approval process by Janssen's Promotional Review Committee ("PRC") or its equivalent. Janssen is searching for and producing accessible and relevant PRC records.

Janssen further responds that between approximately 2003 and 2011, the Department of Justice ("DOJ") and OIG conducted an investigation that involved, among other topics, the medical education and patient support services challenged by Plaintiff, including services that Plaintiff defines as IOI Support Programs. As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The investigation was closed, and the DOJ and OIG did not take any action against Janssen, despite knowing about the patient support programs. Given the Government's extensive knowledge of Janssen's medical education and patient support services, including services that Plaintiff defines as IOI Support Programs, and the fact that the Government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable

statutory and regulatory requirements, including the requirements of the AKS and FCA. Thus, Relator cannot demonstrate falsity, scienter, intent, or materiality.

**INTERROGATORY NO. 21:**

In Affirmative Defense No. 4 of your Answer to the Second Amended Complaint you contend that “Janssen support services related to Remicade and Simponi ARIA did not violate the AKS for reasons that include, but are not limited to, the fact that Janssen support services related to Remicade and Simponi ARIA did not have substantial independent value.” Set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

**RESPONSE TO INTERROGATORY NO. 21:**

In addition to the foregoing General Objections, Janssen objects to this Interrogatory as untimely under the Court’s order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

Janssen further objects to Plaintiff’s Interrogatories as in violation of Local Rule 26.1(c) and the Court’s order dated December 18, 2020, both of which limit each party to 25 interrogatories. Plaintiff served 18 enumerated interrogatories on January 19, 2021, which Plaintiff amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; and 14 enumerated interrogatories on May 19, 2021; bringing her total number of interrogatories to 33. Janssen responded to Plaintiff’s interrogatories on February 18, 2021, May 3, 2021, June 22, 2021, and August 4, 2021. When factoring in sub-parts of Plaintiff’s Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Plaintiff has served, and Defendant has responded to, at least 74 Interrogatories. When incorporating the subparts to Plaintiff’s Definitions and Instructions to

her Interrogatories, Plaintiff has served, and Defendant has responded to, over 600 Interrogatories.

Janssen further objects to this Request to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen further objects that this Interrogatory is vague, ambiguous, overbroad, and unduly burdensome in its reference to “all facts, documents, and evidence.” *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) (“Contention interrogatories may be held unduly broad if they ask in an undifferentiated way for ‘all’ facts or witnesses that support an opposing party’s case.”). Janssen also objects to this Interrogatory in its entirety as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence.

Janssen further objects to this Interrogatory on the ground that it is a premature contention interrogatory. Discovery and investigation are ongoing, and Janssen therefore objects to this Interrogatory to the extent it purports to require a response prior to the period immediately before the end of this phase of fact discovery. *See generally McCarthy v. Paine Webber Group, Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996).

Janssen further objects that the AKS and other statutes and regulations at issue in this matter speak for themselves. Janssen further objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at \*3 (D. Mass. Feb. 6, 2018); *Iantosca v. Benistar Admin Servs., Inc.*, No. 08-11785-NMG, 2012 WL 220224, at \*3 (D. Mass. Jan. 24, 2012).

Janssen further objects to this Interrogatory on the grounds that it has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

Notwithstanding the foregoing general and specific objections, Janssen responds that, on multiple occasions, OIG and judicial guidance have found that the AKS is not implicated by comparable product support programs and services, including as detailed in Janssen's Motion to Dismiss, at 6, 8–12. Under this OIG and judicial guidance, the medical education and patient support services challenged by Plaintiff did not have substantial independent value because the information contained within presentations, documents, and programming Plaintiff and other Janssen-employed ABSs provided to physician practices was compiled from and available through publicly available sources, including but not limited to websites of government agencies and medical societies, as well as articles published in *The Rheumatologist* magazine (published by the American College of Rheumatology) and other publicly available journals. Services with nominal value do not qualify as remuneration under the AKS. *See, e.g.*, 2003 OIG Guidance, 68 Fed. Reg. at 23,735 (“Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute.”). Representative, non-exhaustive examples of such sources are identified in Janssen's Motion to Dismiss, at 12–14 & App. A–O. Additional publicly available sources are included in the documents produced at JANSSEN.019.0000001 to JANSSEN.019.0003518 and JANSSEN.020.0000001 to JANSSEN.020.0000165.<sup>1</sup> As the OIG has made clear in other contexts, services offered to

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<sup>1</sup> To the extent this Interrogatory seeks additional examples of publicly available non-proprietary content, Janssen objects that it would be unduly burdensome and disproportionate to the needs of

healthcare providers that are publicly or otherwise freely available are by definition of nominal, and not substantial, value. *See, e.g.*, OIG Adv. Op. No. 07-16, 2007 WL 6400843, at \*3 (finding patient education videos to have nominal remunerative value under the AKS when “[s]imilar information content is available on the Internet and from other public sources without charge”).

Janssen further responds that the medical education and patient support services challenged by Plaintiff did not have substantial independent value because they did not provide value independent from the medications they were related to: Remicade and Simponi ARIA. Many if not all of the medical education and patient support services at issue were directly related to Remicade and Simponi ARIA. *See, e.g., U.S. ex rel. Suarez v. AbbVie, Inc.*, No. 15-CV-08928, 2019 WL 4749967, at \*7 (N.D. Ill. Sept. 30, 2019) (dismissing claims for failure to plead sufficiently that alleged goods or services were independent, discussing OIG guidance).

Janssen further responds that the medical education and product support services did not allow the recipients to avoid or reduce expenses they would incur in the ordinary course of business.

#### **INTERROGATORY NO. 22:**

In Affirmative Defense No. 8 of your Answer to the Second Amended Complaint you contend that “any false claims that Janssen allegedly submitted or caused to be submitted and any false record or statement that Janssen allegedly made, used, or caused to be made or used to get a claim paid were not done knowingly.” Set forth all facts, documents, and evidence that support your contention and identify the witnesses who have knowledge concerning your contention.

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the case for Janssen to attempt to compile such information, which is equally available to Plaintiff from public and third-party sources.

**RESPONSE TO INTERROGATORY NO. 22:**

In addition to the foregoing General Objections, Janssen objects to this Interrogatory as untimely under the Court's order dated December 18, 2020, which required written discovery requests to be served by January 22, 2021.

Janssen further objects to Plaintiff's Interrogatories as in violation of Local Rule 26.1(c) and the Court's order dated December 18, 2020, both of which limit each party to 25 interrogatories. Plaintiff served 18 enumerated interrogatories on January 19, 2021, which Plaintiff amended per Court order on May 14, 2021; 1 enumerated interrogatory on May 13, 2021; and 14 enumerated interrogatories on May 19, 2021; bringing her total number of interrogatories to 33. Janssen responded to Plaintiff's interrogatories on February 18, 2021, May 3, 2021, June 22, 2021, and August 4, 2021. When factoring in sub-parts of Plaintiff's Interrogatories and Amended Interrogatories, which per the Federal Rules of Civil Procedure should be counted independently, Plaintiff has served, and Defendant has responded to, at least 74 Interrogatories. When incorporating the subparts to Plaintiff's Definitions and Instructions to her Interrogatories, Plaintiff has served, and Defendant has responded to, over 600 Interrogatories.

Janssen further objects to this Interrogatory to the extent that it requests information protected by the attorney-client privilege, attorney work product protection, or any other applicable privilege or protection.

Janssen further objects that this Interrogatory is vague, ambiguous, overbroad, and unduly burdensome in its reference to "all facts, documents, and evidence." *See generally* Wright & Miller, Fed. Prac. & Proc. Civ. § 2167 (3d ed.) ("Contention interrogatories may be held unduly broad if they ask in an undifferentiated way for 'all' facts or witnesses that support an

opposing party's case.”). Janssen also objects to this Interrogatory in its entirety as overbroad, unduly burdensome, not proportional to the needs of the case, and not reasonably calculated to lead to the discovery of admissible evidence.

Janssen also objects to this Interrogatory on the ground that it is a premature contention interrogatory. Discovery and investigation are ongoing, and Janssen therefore objects to this Interrogatory to the extent it purports to require a response prior to the period immediately before the end of this phase of fact discovery. *See generally McCarthy v. Paine Webber Group, Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996).

Janssen further objects that the AKS and other statutes and regulations at issue in this matter speak for themselves. Janssen further objects that this Interrogatory improperly calls for a legal conclusion, which is not permitted by Federal Rule 33. *See Martin v. Evans*, No. 16-CV-11362-PBS, 2018 WL 10247394, at \*3 (D. Mass. Feb. 6, 2018); *Iantosca v. Benistar Admin Servs., Inc.*, No. 08-11785-NMG, 2012 WL 220224, at \*3 (D. Mass. Jan. 24, 2012).

Janssen further objects to this Interrogatory on the grounds that it has not received complete responses to its subpoenas to government agencies. Janssen objects to providing a response to this Interrogatory unless and until the government agencies complete their production of documents.

Notwithstanding the foregoing general and specific objections, Janssen responds that it is Plaintiff's burden to establish that the challenged medical education and product support services led to the “knowing” submission of allegedly false claims under the statutory requirements of the FCA and as that term has been defined by relevant case law, and Plaintiff cannot meet this burden.



Janssen further responds that, at the time the product support services were provided, and through the present, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. The legality of the programs is supported by the publicly available guidance materials from relevant government agencies, which consistently confirmed that product support services do not constitute unlawful kickbacks unless they provide substantial and independent value to the prescriber. *See* 68 Fed. Reg. 23,731, 23,735 (May 5, 2003); *see also* Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed.Reg. 79,202, 79,210 (Dec. 27, 2013). Furthermore, on multiple occasions, the OIG has found that the AKS is not implicated by comparable programs and services. *See* OIG Advisory Opinions and judicial decisions cited in Janssen's Motion to Dismiss, 6, 8–12.

Janssen further responds that its HCC department established practices and standards applicable to ABS engagement with physician practices. Tom Cornely served as an HCC officer supporting the Immunology franchise during the time period when Janssen ABSs provided medical education and patient support services to rheumatology and gastroenterology physician practices. Janssen searched for and is producing accessible and relevant, non-privileged guidance and policies that can be located after a reasonable search.

Janssen further responds that medical education and patient support resources go through an approval process by Janssen's PRC or its equivalent. Janssen is searching for and producing accessible and relevant PRC records.

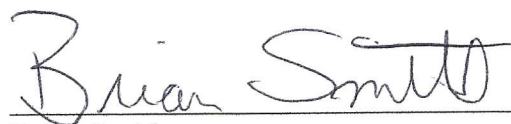
Janssen further responds that between approximately 2003 and 2011, the DOJ and OIG conducted an investigation that involved, among other topics, the medical education and patient

support services challenged by Plaintiff, including services that Plaintiff defines as IOI Support Programs. As part of this investigation, DOJ and OIG reviewed and analyzed the patient support services that Relator now claims are kickbacks. The investigation was closed, and the DOJ and OIG did not take any action against Janssen, despite knowing about the patient support programs. Given the Government's extensive knowledge of Janssen's medical education and patient support services, including services that Plaintiff defines as IOI Support Programs, and the fact that the Government has not taken any action against Janssen, Janssen reasonably believed that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the AKS and FCA. Thus, Relator cannot demonstrate falsity, scienter, intent, or materiality.

**VERIFICATION**

I am the Vice President, Immunology Portfolio Strategy at Janssen Biotech, Inc. I am authorized to make this verification on behalf of Janssen Biotech, Inc. I have read Defendant's foregoing responses to Plaintiff-Relator Julie Long's Interrogatory Nos. 20-22 and know their contents. I am informed and believe that the matters stated therein are true and on that ground certify or declare under penalty of perjury that the same are true and correct.

Executed on March 14, 2022.

A handwritten signature in cursive script that reads "Brian Smith". The signature is written in dark ink and is positioned above a horizontal line.

Brian Smith

**AS TO OBJECTIONS AND RESPONSES:**

Dated: March 17, 2022

*Ethan M. Posner*

Ethan M. Posner (admitted *pro hac vice*)  
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*Attorneys for Defendant Janssen Biotech, Inc.*

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served by electronic mail on March 17, 2022, to the following counsel of record:

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